

Notice of Allowability

Application No.

09/993,159

Examiner

Michael C. Wilson

Applicant(s)

LOVENBERG ET AL.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the appeal brief filed 6-3-05.
2. ☒ The allowed claim(s) is/are 1,2 and 5-7.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____



MICHAEL WILSON
PRIMARY EXAMINER

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Linda Evans on 11-17-05.

It is noted that the limitation of "insensitivity to amnesic effects of scopolamine as demonstrable in a passive avoidance test" can be found on pg 10, lines 10-17.

The application has been amended as follows:

Claims 2 and 3 have been canceled.

In claim 1, the term --homozygous-- has been inserted after the phrase "somatic and germ cells comprise a".

In claim 1, the term --homozygous-- has been inserted after the phrase "non-functional histamine H3 receptor gene, and wherein said".

The following is an examiner's statement of reasons for allowance:

Claim Rejections - 35 USC § 101

The rejection of claims 1-7 under 35 U.S.C. 101 because the claimed invention lacks patentable utility has been withdrawn.

Applicants argue the phenotype of the mice claimed reflects a known function of the H3 receptor in cholinergic pathways modulating memory function or cognitive

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processes (§ bridging pg 9-10). Applicants provide Durant (WO 95/11894) taught histamine H3 receptor antagonists were used to treat dementia disorders such as Alzheimer's. Applicants provide Perez-Garcia (Psychopharm., 1999, Vol. 142, pg 215-220) who tested histamine H3 receptor ligands in experimental *in vivo* models of anxiety and depression. Applicants argue the specification taught using the mice in passive avoidance tests to study the efficacy of experimental histamine H3 receptor antagonists (pg 17-18) and the effects of histamine H3 receptor antagonists on sleep-wake states (pg 16). In addition, pg 9, lines 17-27, describe the H3 receptor as being linked to the regulation of sleep/waking behavior and studies with H3 antagonists that increase wakefulness *in vivo*. The specification goes on to describe using the mice claimed in sleep/waking behavior assays. Pg 10, lines 1-25, describes the H3 receptor as being linked to cholinergic regulation of memory and cognitive processes. The specification goes on to describe using the mice claimed in "step-through passive avoidance test." The above arguments along with pg 9, 10 and 16-18 of the specification are adequate to overcome the utility rejection.

For the record, Harris (DDT, June 2001, Vol. 6, No. 12, pg 628-636) was not found persuasive because it does not link the H3 receptor to any H3 receptor function, H3 receptor antagonists or H3 receptor-related *in vivo* assays known in the art at the time of filing.

Claim Rejections - 35 USC § 112

The rejection of claims 1-7 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, has been withdrawn.

Applicants' arguments under enablement refer to utility under 101 and fail to recognize the legal standard for enablement. However, in order to allow the case, applicants' arguments have been envisioned as addressing the "how to use" clause of the enablement statute.

The mice claimed have a phenotype that reflects a known function of the H3 receptor in cholinergic pathways modulating memory function or cognitive processes (§ bridging pg 14-15 of appeal brief). Applicants provide Durant (WO 95/11894) taught histamine H3 receptor antagonists were used to treat dementia disorders such as Alzheimer's (§ bridging pg 15-16 of appeal brief). Applicants provide Perez-Garcia (Psychopharm., 1999, Vol. 142, pg 215-220) who tested histamine H3 receptor ligands in experimental *in vivo* models of anxiety and depression. Applicants argue the specification taught using the mice in passive avoidance tests to study the efficacy of experimental histamine H3 receptor antagonists (pg 17-18 of original specification) and the effects of histamine H3 receptor antagonists on sleep-wake states (pg 16 of original specification). In addition, pg 9, lines 17-27, of the original specification describe the H3 receptor as being linked to the regulation of sleep/waking behavior and studies with H3 antagonists that increase wakefulness *in vivo*. The specification goes on to describe using the mice claimed in sleep/waking behavior assays. Pg 10, lines 1-25, of the original specification describe the H3 receptor as being linked to cholinergic regulation

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of memory and cognitive processes. The specification goes on to describe using the mice claimed in "step-through passive avoidance test." The above arguments along with pg 9, 10 and 16-18 of the original specification are adequate to overcome the enablement rejection regarding how to use the mice claimed.

The rejection regarding enablement of disrupting any histamine H3 receptor gene as claimed has been withdrawn. Applicants did not argue this rejection. However, in order to allow the case, the rejection has been reconsidered.

H3 receptors encompass at least 2 types (West of record, 1990, Mol. Pharmacol., Vol. 38, pg 610-613). While the specification does not teach which H3 receptor was disrupted or which H3 receptor subtype is linked to insensitivity to amnesic effects of scopolamine as demonstrable in a passive avoidance test, one of skill could assay to determine which H3 receptor caused such a phenotype. Therefore, the specification provides adequate guidance for one of skill to determine which H3 receptor subtype must be disrupted to cause the phenotype claimed. It is recognized that the claimed invention may encompass non-operative embodiments.

For clarity, the final office action of 5-18-04 stated that the phrase "the blastocysts" in claim 5, item c) lacked antecedent basis. The statement was in error because the phrase did have antecedent basis rejection as amended on 2-24-04 (and duplicated in the amendment filed 3-1-04).

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on 571-272-0735.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson



MICHAEL WILSON
PRIMARY EXAMINER